K082251

APR - 8 2009

Summary of Safety & Effectiveness
SYNCHRON® Systems
Microalbumin (MA) Reagent

1.0 **Submitted By:**

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2.0 **Date Submitted:**

August 7, 2008

3.0 **Device Name(s):**

3.1 **Proprietary Names**
SYNCHRON® Systems Microalbumin (MA) Reagent

3.2 **Classification Name**
Albumin immunological test system (21 CFR § 866.5040)

4.0 **Predicate Device:**

| Candidate(s) | Predicate | Manufacturer | Docket Number |
|---|---|---|---|
| Synchron Systems Microalbumin (MA) Reagent | IMMAGE Immunochemistry Systems Microalbumn (MA) Reagent | Beckman Coulter, Inc | K965035 |

5.0 **Description:**

Synchron Systems Microalbumin (MA) reagent is intended for the quantitative determination of albumin in urine. MA reagent is used to measure the albumin concentration by a turbidimetric method. In the reaction, albumin combines with specific antibody to form insoluble antigen-antibody complexes. The Synchron System(s) automatically proportions the appropriate sample and reagent volumes into the cuvette. The ratio used is one part sample to 24 parts reagent. The system monitors the change in absorbance at 380 nanometers. This change in absorbance is proportional to the concentration of albumin in the sample and is used by the system to calculate and express albumin concentration based upon a non-linear calibration curve.

6.0 **Intended Use:**

MA reagent, when used in conjunction with SYNCHRON CX® System(s) and SYNCHRON CX® MA Calibrator, is intended for the quantitative determination of albumin (MA) concentration in human urine. Measurement of albumin in urine aids in the diagnosis of kidney dysfunction.

7.0 **Comparison to Predicate(s):**

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

| | Similarities | |
|---|---|---|
| Synchron Microalbumin (MA) Reagent | Intended Use | Same |
| | Antibody | Goat anti-human albumin polyclonal Ab. Same as Immage MA Reagent |
| | Buffer | Phosphate buffer with PEG |
| | Single point adjusted Calibration | MA on LX and DxC platforms and IMMAGE MA use single point adjusted non-linear calibration. |
| | Differences | |
| Synchron Microalbumin (MA) Reagent | Initial measuring range | Immage: 0.2 – 4.0 mg/dL<br>Synchron Systems: 0.2 – 30 mg/dL |
| | Extended measuring range | Immage: 4.0 – 864.0 mg/dL (achieved via on-line dilutions)<br>Synchron Systems: 24 – 97 mg/dL (achieved via smaller sample size) |
| | Calibration | MA on Sychron CX systems uses 6 level non-linear calibration curve. |

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison, stability, linearity, and imprecision experiments.

Method Comparison Study Results

| Candidate | Slope | Intercept | R | N | Predicate Method |
|---|---|---|---|---|---|
| CX Systems Synchron Microalbumin (MA) Reagent (0.4 to 26.1 mg/L) | 0.990 | -0.11 | 0.987 | 111 | IMMAGE Microalbumin (MA) Reagent |

SYNCHRON CX Systems Precision Study Results

| Sample | Mean (mg/dL) | S.D. (mg/dL) | %C.V. | N |
|---|---|---|---|---|
| Within-Run Imprecision | | | | |
| Level 1 | 0.8 | 0.08 | 9.7 | 80 |
| Level 2 | 3.0 | 0.14 | 4.5 | 80 |
| Level 3 | 40.1 | 0.42 | 1.0 | 80 |
| Total Imprecision | | | | |
| Level 1 | 0.8 | 0.13 | 16.3 | 80 |
| Level 2 | 3.0 | 0.23 | 7.5 | 80 |
| Level 3 | 40.1 | 0.59 | 1.5 | 80 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter Inc.
c/o Ms. Marine Boyajian
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Brea, CA 92822-8000

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Re: k082251
Trade/Device Name: SYNCHRON Systems MicroAlbumin (MA) Reagent
Regulation Number: 21 CFR 866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: Class II
Product Code: DCF
Dated: March 03, 2009
Received: March 04, 2009

Dear Ms. Boyajian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

# Indication for Use

510(k) Number (if known): K082251

Device Name: SYNCHRON® Systems Microalbumin (MA) Reagent

Indication For Use:

MA reagent, when used in conjunction with SYNCHRON CX® System(s) and SYNCHRON CX® MA Calibrator, is intended for quantitative determination of Albumin concentration in human urine. Measurement of albumin in urine aids in the diagnosis of kidney dysfunction.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082251